

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Lamisil Cream 1% w/w

Active ingredient and its concentration in a dosage unit:

Terbinafine Hydrochloride 1% w/w

Inactive ingredients and allergens in the preparation - please see section 6 and section 2 under the title "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

The preparation has a broad-spectrum antifungal activity for the treatment of fungal infection of the skin.

Therapeutic class: antifungal.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional components the medicine contains, which are listed in section 6.

Special warnings regarding the use of the medicine

Before treatment with Lamisil Cream, tell your doctor if you have any other illness or allergies.

- Lamisil Cream is not recommended for use in children under the age of 12.
- Lamisil Cream is intended for external use only. Avoid contact with the eyes. In case of contact of the preparation with the eyes, rinse your eyes immediately and thoroughly under running water. If you feel any discomfort in your eyes, refer to your doctor.
- In the event of extensive athlete's foot or if the fungal infection also involves the nails, refer to your doctor.
- Do not apply additional medicines on the treated skin areas.

Children and adolescents

No information is available regarding the safety and efficacy of using this preparation in children under the age of 12.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Pregnancy and breastfeeding

Pregnancy

Do not use Lamisil Cream if you are pregnant, unless recommended by a doctor.

If you are planning to become pregnant, consult your doctor before using Lamisil Cream.

Breastfeeding

Do not use Lamisil Cream if you are breastfeeding. Infants must not come in contact with the area being treated with the preparation.

Driving and operating machinery

Lamisil Cream has no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

Lamisil Cream contains:

- 15 mg of Benzyl alcohol in a 15 gram package and 30 mg in a 30 gram package, equivalent to 10 mg/gram. Benzyl alcohol may cause allergic reactions and local irritation of the skin.
- Cetyl alcohol – may cause skin reactions, such as eczema (contact dermatitis).
- Stearyl alcohol – may cause skin reactions, such as eczema (contact dermatitis).

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Before using Lamisil Cream, wash the affected area and dry it thoroughly.

Lamisil Cream is intended for adults and children above the age of 12. Lamisil Cream can be applied once or twice a day (morning and/or evening). Gently apply a thin layer of Lamisil Cream on and around the affected area.

The generally accepted dosage is:

- For athlete's foot that appears between the toes (Tinea Pedis), fungal infection of the groin, fungal infection of the body – apply once a day for one week.
- For athlete's foot that appears on the sole of the foot and/or on the sides of the foot [Tinea Pedis Plantaris (Moccasin Type)] – apply twice a day for two weeks.
- For skin candidiasis – apply once to twice a day, for one week.
- For pityriasis versicolor (sun fungus) – apply once to twice a day, for two weeks.

If the treatment is within the folds of the skin, the area can be covered with a gauze dressing. Covering the area is especially recommended at night. The gauze should be replaced with each application.

Wash your hands after each application on the affected area.

Do not exceed the recommended dose.

To prevent re-infection, the fungal infection should be treated according to the instructions in this leaflet.

If your condition does not improve after one week, consult your doctor.

The fungal infection should be treated with the dosages indicated in this leaflet. If you feel that the effect of the medicine is too strong or too weak, refer to the doctor or pharmacist.

Do not swallow, this medicine is intended for external use only.

If you have taken an overdose or if a child has accidentally swallowed this medicine, go immediately to a hospital emergency room, and take the package of the medicine with you.

If you forget to apply the medicine at the required time, do not apply a double dose. Apply the next dose at the regular time and consult a doctor.

Do not take medicines in the dark! Check the label and the dosage every time you take the medicine. Wear glasses if you need them.

How can you contribute to the success of the treatment?

To avoid athlete's foot, the following steps should be taken:

- Clothes that have been in contact with the affected area should be changed every day.
- Avoid wearing tight clothing or such clothing that does not allow airing of the skin.
- The affected area should be gently dried after washing.
- Change towels every day.
- If you suffer from athlete's foot, do not walk barefoot. In addition, your shoes should be powdered or sprayed with products intended for use against athlete's foot. Wash your hands thoroughly after using the preparation and after contact with the affected skin to avoid spreading the infection.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Lamisil Cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a doctor immediately if you experience one or more of the following effects, which may indicate an allergic reaction:

- Difficulty breathing and swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin accompanied by redness or raised blisters

Side effects of the immune system:

Very rare – side effects that occur in less than one out of 10,000 users: hives

- Side effects of the eyes:
- Rare – side effects that occur in 1-10 out of 10,000 users: irritation
- Side effects of the skin:
- Common – side effects that occur in 1-10 out of 100 users: peeling, itch
- Uncommon – side effects that occur in 1-10 out of 1,000 users: sores, scabs, skin disorders, change in skin color, redness, burning sensation
- Rare – side effects that occur in 1-10 out of 10,000 users: dry skin, eczema, dermatitis due to contact with the preparation
- Very rare – side effects that occur in less than one out of 10,000 users: rash or pimples on the skin
- General side effects and side effects in the treated area:
- Uncommon – side effects that occur in 1-10 out of 1,000 users: pain, pain or irritation at the treated area
- Rare – side effects that occur in 1-10 out of 10,000 users: worsening of the fungal infection
- **If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**
- Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>
- **5. How to store the medicine?**
- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: store at a temperature below 30°C.
- **Once opened for the first time, the product may be used for 12 months.**
- **6. Additional information**
- **In addition to the active ingredient, the medicine also contains** Isopropyl myristate, Polysorbate 60, Stearyl alcohol, Cetyl alcohol, Cetyl Palmitate, Sorbitan Stearate, Benzyl alcohol, Sodium hydroxide, Purified Water.
- **What does the medicine look like and what are the contents of the package**
- Lamisil Cream is a smooth, glossy, white cream. The cream is marketed in Israel in packages of 15 grams and 30 grams. Not all package sizes may be marketed.
- **Marketing authorization holder and address**
- Chemipal LTD, 44 Giborei Israel st., Netanya 4250432
- **Name and address of the manufacturer**
- Karo Healthcare AB, Box 16184, 103 24, Stockholm, Sweden.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 115-55-27562-05
- Revised in March 2025.